

Impact Nerium Oleander on Symptoms and Mortality: A Feasibility Study

A The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT04486144

Recruitment Status : Enrolling by invitation

First Posted : July 24, 2020

Last Update Posted : July 24, 2020

Sponsor:

HealthQuilt

Collaborators:

The Schull Institute

Texas A&M University

The Hildebrand Fund at the Greater Houston Community Foundation

Baylor College of Medicine

The University of Texas Health Science Center, Houston

University of Maryland, College Park

Information provided by (Responsible Party):

HealthQuilt

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[Tabular View](#)

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Study Description

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Brief Summary:

Assess the impact of a proprietary extract of Nerium oleander on COVID-19 symptoms and mortality in COVID-19 positive patients and their close contacts compared to controls that did not receive the extract.

Condition or disease	Intervention/treatment	Phase
Covid19 Positive Patient	Other: Proprietary extract of Nerium oleander	Not Applicable
Covid19 Close Contact		

Detailed Description:

This is an exploratory study based on positive in-vitro, and in-vivo (animals and humans). Up to 100 patients that are COVID-19 positive in the ambulatory setting will be invited to participate. After informed consent is obtained, patients will be in either the Intervention Group (receive extract) or Comparison Group (did not receive extract). A baseline assessment and record review will be conducted to assure eligibility criteria. Patients in the Intervention Group will be given .5 ml (6.25 mg of extract) every 6 hours for 5 days, total of 25 mg per day / 125 mg for 5 days. Patient vital signs (temperature, pulse oximetry, blood pressure) and CDC symptoms / side effects will also be tracked. A dedicated medical oversight team with 24 / 7 access to care will be provided to monitor safety and tolerance. Patients will be followed for 10 days. Baseline antibody, RT-PCR, and live virus will be collected on Day 1, Day 5, and Day 10. A Data Monitoring Committee at the Schull Institute will meet weekly to review data.

Study Design

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Study Type : Interventional (Clinical Trial)
Estimated Enrollment : 100 participants
Allocation: Non-Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Treatment
Official Title: Impact of a Proprietary Extract of Nerium Oleander on Symptoms and Mortality :A Feasibility Study
Actual Study Start Date : May 20, 2020
Estimated Primary Completion Date : September 1, 2020
Estimated Study Completion Date : September 1, 2020

Arms and Interventions

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Arm	Intervention/treatment
Experimental: COVID19 Positive: Intervention Group (Receive extract)	Other: Proprietary extract of Nerium oleander This is a proprietary extract of Nerium

Arm	Intervention/treatment
These are patients that are COVID19 positive who elect to try the extract.	oleander that is 6.25 ug per 0.5 ml of suspension. It is administered sublingually every six hours for 5 days. The daily dose is 25 ug and the 5 day dose is 125 ug.
<p>No Intervention: COVID19 Positive: Comparison Group (Do NOT receive extract)</p> <p>These are patients that are COVID19 positive who do NOT elect to try the extract</p>	
<p>Experimental: COVID19 Exposed: Intervention Group (Receive extract)</p> <p>These are patients that are COVID19 negative at the start, live with a COVID19 positive patient and who elect to try the extract.</p>	<p>Other: Proprietary extract of Nerium oleander</p> <p>This is a proprietary extract of Nerium oleander that is 6.25 ug per 0.5 ml of suspension. It is administered sublingually every six hours for 5 days. The daily dose is 25 ug and the 5 day dose is 125 ug.</p>
<p>No Intervention: COVID19 Exposed: Comparison Group (Do NOT receive extract)</p> <p>These are patients that are COVID19 negative at the start, live with a COVID19 positive patient and who elect to NOT try the extract.</p>	

Outcome Measures

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Primary Outcome Measures :

1. COVID19 symptoms [Time Frame: Every 6 hours for 10 days]

The CDC list of symptoms and "other".

2. Mortality [Time Frame: 10 days from enrollment into the Study, e.g. Day 10]

A patient in any arm that dies.

Secondary Outcome Measures :

1. COVID19 Live Virus [Time Frame: Day 1, Day 5, Day 10]

COVID19 Live Virus Nasopharyngeal swab performed by UTMB, Texas

2. RT-PCR COVID19 Test [Time Frame: Day 1, Day 5, Day 10]

RT-PCR Nasopharyngeal swab performed by Fulgent, California

Eligibility Criteria

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Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies.](#)

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Age 18
- COVID 19 positive or close contact of COVID 19 positive
- No use of cardiac glycosides or other antiarrhythmic medications

Exclusion Criteria:

- No use of cardiac glycosides or other antiarrhythmic medications
- No allergy to coconut oil

Contacts and Locations

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To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):
NCT04486144

Locations

United States, Texas

KDunn and Associates, PA, dba Healthquilt
Houston, Texas, United States, 77055

Sponsors and Collaborators

HealthQuilt
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The Hildebrand Fund at the Greater Houston Community Foundation
Baylor College of Medicine
The University of Texas Health Science Center, Houston
University of Maryland, College Park

Investigators

Principal Investigator: Kim Dunn, MD, Ph.D. KDunn and Associates, PA dba Healthquilt

More Information

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Additional Information:

Plante KS, Plante JA, Fernandez D, et al. Prophylactic and therapeutic inhibition of in vitro SARS-CoV-2 replication by Oleandrin. *bioRxiv*. July 15, 2020. Cold Spring Harbor Laboratory. [EXIT](#)

Responsible Party: HealthQuilt

ClinicalTrials.gov Identifier: [NCT04486144](#)
Other Study ID Numbers: 052020
First Posted: July 24, 2020 [Key Record Dates](#)
Last Update Posted: July 24, 2020
Last Verified: July 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes
Plan Description: KDunn and Associates, PA will de-identify data and archive it at The Schull Institute Data Archive at the University of Texas School of Biomedical Informatics.
Supporting Materials: Study Protocol
Statistical Analysis Plan (SAP)
Informed Consent Form (ICF)
Clinical Study Report (CSR)
Time Frame: October 2020
Access Criteria: Need to have a specific question or plan to study further.
URL: <http://www.theschullinstitute.org>

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by HealthQuilt:

Covid19
Nerium oleander
Clinical symptoms
Mortality